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MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER SHEN, WU CHENG WINSTON	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/501,289	<b>Applicant(s)</b> PETERSEN ET AL.	
	<b>Examiner</b> Wu-Cheng Winston Shen	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-13, 15, 16, 18 and 32-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-13, 15, 16, 18, and 32-38 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's response received on 6/18/07 has been entered. Claims 4, 14, 17, and 19-31 were cancelled. Claims 1-3, 6-13, 15, and 18 were amended. Claims 32-39 are newly added. Claims 1-3, 5-13, 15, 16, 18, and 32-39 are pending. Claims 1-3, 5-13, 15, 16, 18, and 32-39 are currently under examination.

This application 10/501,289 filed on June 29, 2005 is a 371 of PCT/EP03/00518 filed on 01/16/1003, and priority of foreign application DENMARK PA 200200079 filed on 01/17/2002.

### ***Claim Objections***

1. Previous objection to claims 2, 3, 5-13, 15, and 18 because of the following informalities: the phrases "A cell" and "An immortalized cell" recited in claims 2-13, and 15 should recite "The cell" and "The immortalized cell", and the phrase "A method" recited in claim 18 should recite "The method", is *withdrawn* because claims 2, 3, 6-13, 15, and 18 have been amended.

Specifically, the articles "A" or "An" recited in claims 2, 3, 6-13, 15 have been editorially changed to "The" to clarify the dependency of claims.

Upon further consideration, the objection to claim 5 is withdrawn because claim 5 reads on a cell population (instead of a cell) composed of cells according to claim 1.

Claim 1 is objected to because of the following informalities: The claim, as written is grammatically improper. The term "being" in line 4 should read as "is". Appropriate correction is required.

2. Claim 39 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 16.

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When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

It is noted that both claims 19 and claim 16 recite the phrases “The immortalized cell line” and “ which is deposited in accordance with the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) on October 9, 2001 and has obtained the accession number DSM ACC 2529”. In this regard, applicants attention is drawn to the following statements: When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983), and *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

### ***Claim Rejection - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 6-13, 15, 16, 18, and 32-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. *This rejection is necessitated by the claim amendments.*

It is noted that claim 6 depend from claim 4, which has been canceled. Claims 7-13, 15 and 16 depend from claim 6.

Claim 6 recites the limitation "*the* immortalized cell line derived from claim 4" and claims 7-13, 15, and 16 depend from claim 6. There is insufficient antecedent basis for this limitation because claim 4 has been cancelled.

Amended claim 18 recites the limitation "*said cells*" in the limitation "thereby obtaining an enriched population of cells which are capable of proliferating and differentiating into cells of mammary gland luminal epithelial and myo-epithelial cell lineages, *said cells* being capable of forming a cell culture comprising cells which are positive staining for the luminal epithelial marker ESA (ESA+) and negative staining for sialomucin (MUC-), so-called (ESA+/MUC-) cells". It is unclear if the recited "*said cells*" refer to "an enriched population of cells" or "cells of mammary gland luminal epithelial and myo-epithelial cell lineages". Newly added claims 32-38 depend from claim 18.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Previous rejection of claim 16 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement; the claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is **withdrawn** because Applicant has submitted on 06/18/2007, in response to Non-Final office action mailed on

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03/16/2007, a Statement and Declaration attesting that the deposit was made under the provisions of the Budapest Treaty and assures public availability, and a copy of the deposit certificate and statement of viability from the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ).

*New Matter*

5. Claims 18 and 32-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.* 37 CFR 1.118 (a) states that “No amendment shall introduce **new matter** into the disclosure of an application after the filing date of the application”.

The amended claim 18 contains the terminology “b) passing the cells from the primary culture through an anti-sialomucin column *followed by* retention of the flow-through in an anti-ESA column”. Claims 32-38 depend from claim 18. Literal support for this terminology “passing the cells from the primary culture through an anti-sialomucin column *followed by retention of the flow-through in an anti-ESA column*” recited in claim 18 is not found in the specification. Applicant’s statements (See, second paragraph, Remarks, page 7 of reply filed on 06/18/2007) that support for the amendments and new claim is found throughout the specification, including for instance, Example 2 at pages 24-28, and original claims 2-10 and 16, were found not persuasive.

The specification teaches that (i) the luminal cell population containing the suprabasal ESA<sup>+</sup>/MUC<sup>-</sup> cells was isolated as the flow-through of an anti-sialomucin (MAM6, clone 115D8, Biogenesis Ltd., Poole, UK) column, and plated in Dulbecco's Modified Eagle Medium, and in passage 6, the medium was switched to H14 medium (See paragraph [0120] of instant application), and (ii) the suprabasal epithelial cells (D492, DMSZ no. DMS ACC 2529) were collected in passage 27 by retention of cells by an anti-ESA (VU-1D9, NovoCastra, Newcastle upon Tyne, UK) column (D492, Table III) (See paragraph [0122] of instant application). Therefore, the specification does not teach the amended claim limitation "passing the cells from the primary culture through an anti-sialomucin column *followed by* retention of the flow-through in an anti-ESA column" recited in claim 18, because the cells of passage 27 as disclosed in the specification is not the claimed flow-through of primary culture passing through an anti-sialomucin column as required by the step b) of amended claim 18. The specification discloses using primary cell culture or different passages of cells subject to either anti-sialomucin column or anti-ESA column, and the specification does not disclose explicitly the consecutive use of an anti-sialomucin column followed by retention of the flow-through in an anti-ESA column as claimed. The specification teaches passaging the cells in culture following collection from the anti-sialomucin column and applying the passaged culture to the anti-ESA column as opposed to direct application of the flowthrough from the anti-sialomucin column to the anti-ESA column.

MPEP 2163.06 notes, "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that

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"Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed. If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure" (emphasis added).

6. Claims 1-3, 5-13, 15, 16, 18, and 32-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the



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breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

*The basis for this lack of enablement rejection of claimed immortalized isolated cells derived from luminal epithelial cells of mammary gland and method of enriching the said cells is the presence of ESA (epithelial-specific antigen) marker in cells other than luminal epithelial cells of mammary gland. Thus, expression of ESA is not a marker sufficient for use as an identifying characteristic of the claimed cells.*

The nature of the instant invention is an immortalized isolated cells derived from luminal epithelial cells of mammary gland, which are ESA-positive and MUC-negative (claim 1); a method of enrichment of a population of cells derived from luminal epithelial cells of mammary gland, which are ESA-positive and MUC-negative by recited steps including using primary cell culture or different passages of cells subject to either anti-sialomucin column or anti-ESA column (claim 18).

The breadth of the claims encompass any cells that are ESA-positive since ESA is the only positive identifying characteristics recited and a method enrichment of the said ESA-positive cells by retention of the cells in an anti-ESA column.

The specification discloses identification of "suprabasal" luminal epithelial cells in the breast (See Example 1 of instant application), and the isolation, immortalization and characterization of luminal and suprabasal-derived epithelial cells (See Example 2 of instant application). The specification also discloses the isolated, suprabasal-derived epithelial "stem" or "progenitor" cells as well as the isolated of luminal cells without "stem-cell" properties.

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However, the specification does not provide information whether ESA is *exclusively* expressed in the isolated luminal and suprabasal-derived epithelial cells.

With regard to using the presence of ESA as the only positive identifying characteristic of luminal epithelial cells, it has been shown in the art that the expression of ESA is present in cells other than claimed luminal epithelial cells. For instance, **Li et al.** reported that ESA is detected in pancreatic cancer stem cells (See abstract, Li et al. Identification of pancreatic cancer stem cells. *Cancer Res.* 67(3): 1030-7, 2007). Moreover, **Markaki et al.** reported the expression of ESA in cervical intraepithelial neoplasia and adenocarcinoma (See title and Abstract, Markaki et al., The expression of epithelial specific antigen in cervical intraepithelial neoplasia and adenocarcinoma, *Eur J Gynaecol Oncol.* 25(1): 101-3, 2004). Therefore, the art clearly indicates that the expression of ESA is not specific for the claimed luminal epithelial cells, which renders the claims of instant application **not** enabled. Because cell types other than luminal epithelial cells express ESA, the use of ESA expression as the only identifying characteristic would not be definitive in obtaining the claimed luminal epithelial cells. Thus, the specification has not taught one of skill in the art how to determine when they have achieved the invention.

In view of the lack of guidance, working examples, breadth of the claims, the level of skill in the art and state of the art at the time of the claimed invention was made, it would have required one of skill in the art undue experimentation to make and use the invention as claimed.

7. Claims 1-3, 5-13, 15, 16, 18, and 32-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

The claimed invention as a whole is not adequately described if the claims require essential or critical elements that are not adequately described in the specification and that is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with *sufficient relevant identifying characteristics* such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641,1646 (1998).

This rejection is based on that (i) the ESA-positive is not an identifying characteristic of claimed luminal epithelial cells.

Regarding the expression of ESA is present in cells other than claimed luminal epithelial cells. As discussed in the preceding rejection under 35 USC 112, 1<sup>st</sup> paragraph, **Li et al.** reported that ESA is detected in pancreatic cancer stem cells (See abstract, Li et al. Identification of pancreatic cancer stem cells. *Cancer Res.* 67(3): 1030-7, 2007). Moreover, **Markaki et al.** reported the expression of ESA in cervical intraepithelial neoplasia and adenocarcinoma (See title and Abstract, Markaki et al., The expression of epithelial specific antigen in cervical

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intraepithelial neoplasia and adenocarcinoma, *Eur J Gynaecol Oncol.* 25(1): 101-3, 2004).

Therefore, ESA-positive is not an identifiable characteristic of claimed luminal epithelial cells.

Based on the reason discussed above, the claim(s) of instant application contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

### ***Claim Rejection - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Previous rejection of claims 1-3, 5, 17 and 18 under 35 U.S.C. 102(b) as being anticipated by **Stingl et al.** (Stingl et al., Phenotypic and functional characterization in vitro of a multipotent epithelial cell present in the normal adult human breast. *Differentiation.* 63(4): 201-13, 1998; listed as the last reference in the Information Disclosure Statement filed on 11/5/2004 by the applicants), is ***withdrawn*** because the claims have been amended.

Specifically, claim 1 has been amended to read on “An immortalized isolated cell derived from luminal epithelial cells of a mammary gland”. Sting et al did not teach the recited “immortalized” cells.

Claim 18 has been amended to recite the limitation “ b) passing the cells from the primary culture through an anti-sialomucin column followed by retention of the flow-through in an anti-ESA column”. Sting et al did not the recited step for the enrichment of a population of cells derived from luminal epithelial cells of a mammary gland.

***Claim Rejection - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 1, 4, 6-13, and 15 remain rejected under 35 U.S.C. 103(a) and claims 1-3, 5, 17, and 18, previously rejected under 35 U.S.C. 102(b), as amended are newly rejected under 35 U.S.C. 103(a) as being unpatentable over **Stingl et al.** (Stingl et al., Phenotypic and functional characterization in vitro of a multipotent epithelial cell present in the normal adult human breast. *Differentiation*. 63(4): 201-13, 1998; listed as the last reference in the IDS filed by the applicants) taken with **Wazer et al.** (Wazer et al., Immortalization of distinct human mammary epithelial cell types by human papilloma virus 16 E6 or E7. *Proc Natl Acad Sci U S A*. 92(9): 3687-91, 1995). Previous rejection is ***maintained*** for the reasons of record advanced on pages 7-

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10 of the office action mailed on 6/18/07. *The rejection of claims 1-3, 5-13, 15, and 16, previously rejected under 35 U.S.C. 102(b), is necessitated by claim amendments filed on 06/18/2007 adding new claims.*

***Applicant's arguments***

With respect to the aspect of whether the cited prior art rejection makes *prima facie* case of obviousness by Stingl et al. taken with Wazer et al., Applicant argues that independent claim 1, as amended, is directed to an **immortalized** cell which is capable of forming a cell culture comprising cells which are positive staining for the luminal epithelial marker ESA (ESA+) and negative staining for sialomucin (MUC-), so-called (ESA+/MUC-) cells. Applicant also argues that the inventors of the present application also attempted to immortalize cell's acquired according to Stingl's teachings and were unsuccessful. Applicant further argues that Stingl demonstrates **only** primary cell culture of the cells asserted to have MUC-negative and ESA-positive phenotype. Wazer demonstrates immortalization of mixed cell types derived from mammary tissue and consequently would not recognize failure or problems with immortalization of a particular cell type. Consequently, Applicant argues that, the general teaching of Wazer regarding methods of forming immortalized cells is not sufficient to correct the lack of capability inherently present in Stingl's cells. Hence, even if Wazer's teachings are applied to Stingl's cells, there is not a likelihood of success to generate an immortalized cell of the specified phenotype.

***Response to Applicant's arguments***

It is noted that the incorporation of canceled claim 4 into amended claim 1 regarding the isolated cells being immortalized does not change the essence of the invention, nor did the

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incorporation alter the art rejection under 35 U.S.C. 103(a). It is also noted that Applicant's arguments regarding Applicant's unsuccessfulness in the attempt to immortalize cell's acquired according to Stingl's teachings does not necessarily render the recited epithelial cells unlikely to be immortalized because Applicant does not provide persuasive art-based arguments and fails to provide any evidence indicating that the methods of Stingl would not work. The Examiner further notes that the claims of instant application read on expansion (i.e. cell multiplication without alteration of intrinsic characteristics of the cells, and thereby, the identity of the immortalized cells) of initially isolated immortalized cell derived from luminal epithelial cell of a mammary. Therefore, even if the initial success rate in immortalization by the combined teachings of Stingl et al. and Wazer et al., is low, as Applicant asserted, the isolated immortalized cells can expand into a cell line (or a cell population recited in claim 5) as recited in the claims of instant application. Accordingly, previous rejection is ***maintained*** for the reasons of record advanced on pages 7-10 of the office action mailed on 6/18/07. The rejection of claims 1-3, 5, 17, and 18, previously rejected under 35 U.S.C. 102(b), is necessitated by claim amendments filed on 06/18/2007 adding new claims.

***Conclusion***

10. No claim is allowed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you



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would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Wu-Cheng Winston Shen, Ph. D.

Patent Examiner

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/Valarie Bertoglio, Ph.D./

Primary Examiner

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